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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,040	10/06/2005	Barb Ariel Cohen	V0189.70013US01	2953

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EXAMINER	
PETERSEN, CLARK D	
ART UNIT	PAPER NUMBER
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,040	COHEN ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,25,52,74,80 and 88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,25,52,74,80 and 88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 9, 10, 12, 17-20, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-11, 13-18, and 21-25 of prior U.S. Patent No. 7,018,805 B2, issued Mar. 28, 2006 and filed Aug. 29, 2002. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of Cohen (7,018,805 B2) contains all the elements of claims 1 and 2 of the instant application; however claims 1 and 2 are broader. Instant claims 1 and 2 do not recite that an agent is employed to bind the hydrolyzed starch fragments. Instant claim 3, although broader, is obvious over the teachings of Claim 2 of

Cohen. Instant claim 5, although broader, is rendered obvious by the teachings of claim 3 of Cohen. Instant claim 9, although broader, is rendered obvious by the teachings of claim 6 of Cohen. Instant claim 12, although broader, is rendered obvious by the teachings of claim 7 of Cohen. Instant claim 17 contains the elements of claim 1 of Cohen. Instant claim 18 contains the elements of claim 8 of Cohen. Instant claim 19 contains the elements of claim 9 of Cohen. Instant claim 20, although broader, is rendered obvious by the teachings of Claim 10 of Cohen. Instant claim 25, although broader, is rendered obvious by the teachings of claim 11 of Cohen. Instant claim 6, although broader, is rendered obvious by the teachings of claim 13 of Cohen.

Claims 1-7, 9, 10, 12, 17-20, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 7,018,805 B2, issued Mar. 28, 2006 and filed Aug. 29, 2002 in view of Yook et al (Carbohydrate Res, 2002).

The teachings of Cohen (7,018,805 B2) are discussed above and applied as before.

Cohen (7,018,805 B2) does not expressly teach a method applied to potato starches.

Yook et al teach that a bacterial α-amylase, although acting at different (but measurable) rates, is capable of hydrolyzing both waxy maize and potato starches (see, e.g., Table 3, p. 1116).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the assay of US #7,018,805 B2, which specifies waxy maize starch as a substrate, using potato starch as a substrate instead, as recited in the instant Claim 7, because Cohen teaches that starch, specifically waxy maize starch, can be used as a measurable substrate in a α-amylase assay, and York et al teach that both potato starch and waxy maize starch are susceptible to degradation at easily measurable levels by the same bacterial α-amylase. One would have been motivated to do so, because both types of starch are important commercial products for which an α-amylase assay would be useful.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, one would have had a reasonable expectation of success in practicing the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 80, and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites that the sample can be an "amylase concentrate". An amylase concentrate cannot be a substrate.

Instant claims 80 and 88 recite the use of "fungal incubation buffer". This is not a term readily known to one of ordinary skill in the art, and the term is not defined in the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 9, 12, 13, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Marsili et al (J Agric Food Chem, 1987). Marsili et al teach an α–amylase assay using a radioactive starch substrate, HPLC for fraction separation, and a radioactive flow detector for quantitating uncleaved, radioactive starch substrate. Marsili et al teach that one can obtain radioactive starch substrate from New England Nuclear, for example, that is labeled with ^{14}C (see Radioactive Starch Substrate, p. 305, col. 1, for example). The substrate is fractionated by HPLC before quantitation, reading upon separation from the reaction mixture, and filtering the reaction with a resin. The material measured is remaining unhydrolyzed starch. The α–amylase enzyme was

obtained from commercial sources, in at least one case in a powdered form, reading on an amylase concentrate as the enzyme (see Amylase Preparations, p. 305 col. 1, for example). Additionally, standard calibration curves were prepared using the commercially prepared enzymes, which are of known enzymatic activity (see Amylase Preparations, p. 305, col. 1; see Standard Calibration curves, p. 305, col. 2, to p. 306, col. 1, as examples). Therefore the teachings of Marsili et al are deemed to anticipate the instant claims 1-3, 5, 9, 12, 13, and 20.

Claim 1, 2, 4, 12, 14-16, 20, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Babson (US 3,597,322, issued 3 Aug 1971). Babson teaches a starch labeled with a dye that is susceptible to amylase degradation. After the enzymatic reaction has proceeded, the remaining undigested, dyed starch can be precipated by adding an alcohol/tannic acid solution. The precipitate can then be sedimented by centrifugation, leaving the digested, soluble fragments in solution to be quantitated by optical absorption properties (see Summary of the Invention, col. 3, lines 43-75, for example). Because the reaction proceeds in an aqueous environment, the teachings of Babson read on an aqueous slurry. Therefore the teachings of Babson are deemed to anticipate the instant claims 1,2, 4, 12, 14-16, 20, and 25.

Claims 1-3, 7-11, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Kjaerulf et al (USPGPub 2004/0132039, published 8 July 2004 and claiming priority to PCT/DK02/00160, the abstract of which is WO 02/072876 A3, published 19 Sept. 2002, which claims priority to US provisional 60/275,164, filed 12

Mar 2001). Kjaerulf et al teach a method of measuring amylase activity on fabrics. In particular, they apply amylase to a detectably labeled starch substrate, which releases starch fragments. (see, e.g. Example 5, pp. 29-33). They applied starch to a surface, namely twill, and allowed it to dry. The twill was then punched into 96 well plates and culture medium from a bacterial stock expressing α–amylase was applied to the twill in the culture plates. After incubation, they remove the reaction mixture completely and measure residual fluorescence of the twill (see, e.g., p. 32, lines 18-22). They specifically mention that potato starch is a useful substrate and that the potato starch should be labeled with FITC every 50-300 glucose units (see, e.g., p. 30 lines 8-15). Therefore the teachings of Kjaerulf et al are deemed to anticipate the instant claims 1-3, 7-11, and 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marsili et al (J Agric Food Chem, 1987). The teachings of Marsili are discussed above and applied as before.

Marsili et al do not expressly teach the combination of reagents for their method into a commercial kit. However it is obvious that the reagents are necessary to carry out their method successfully. As discussed above, they also teach that their reagents were obtained from commercial sources. Given their success, and the fact that reagents are already commercially prepared, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine them in a kit. One would have been motivated to do so for the expected benefit of simplifying the gathering of reagents for conducting a successful experiment as taught by Marsili et al.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, one would have had a reasonable expectation of success in practicing the claimed invention.

Claims 74, 80, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babson (US 3,597,322, issued 3 Aug 1971) et al in view of Kjaerulf et al (WO 02/07286 A3, published 19 Sept. 2002, claiming priority to US provisional 60/275,164, filed 12 Mar 2001). The teachings of Babson and Kjaerulf et al are discussed above and applied as before.

Kaerulf et al additionally teach that their method for testing amylase activity on a starch substrate adhering to a solid support can involve an incubation time of anytime between 5 minutes and 2 hours (see p. 31, lines 32-38, for example). Additionally, they contemplate that amylase enzymes would be useful at temperatures between 40 degrees and 60 degrees Celsius (see p. 32, lines 7-10, for example).

Babson teaches that their method, in addition to being amenable to a centrifugation step, can also be performed by filtration of the precipitate out of the reaction mixture (see col. 7, lines 9-11, for example).

Additionally Babson teaches that the reaction is performed in a buffer reading on an incubation buffer (see Examples 1, 2, and 3, cols. 7 and 8, for example). Additionally because the precipitation buffer removes the unhydrolyzed starch from effective contact with the amylase enzyme, it reads upon a stop buffer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the incubation parameters taught by Kaerulf et al (i.e., temperature and time) with the method of separating unhydrolyzed starch taught by Babson, because Kaerulf et al teach that the parameters are effective for conducting an alpha amylase assay, and Babson teaches that precipitation with a solution of alcohol and tannic acid effectively separates reacted product from unreacted substrate. One would have been motivated to do so for the expected benefit that one could achieve flexibility regarding the temperature and time that one used for the assay, and that addition of alcohol/tannic acid porivdes a simple and rapid method of performing an alpha amylase assay.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, one would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
1/3/2007

JON WEBER
SUPERVISORY PATENT EXAMINER